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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,800	08/27/2003	Gisbert Depke	SCH-1920	3937

23599 7590 10/14/2005

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EXAMINER	
FEDOWITZ, MATTHEW L	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,800	DEPKE ET AL.	
	Examiner	Art Unit	
	Matthew L. Fedowitz	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 10, 12 and 17 are pending in this action.

Response to Election/Restrictions

Applicant's election with traverse of Group II directed to pharmaceutical compositions of claims 10, 12 and 17 classified in class 540, subclass 145 in the reply filed on July 29, 2005 is acknowledged. The traversal is on the grounds that the search would not burden the examiner. This is not found persuasive because these inventions have acquired a separate status in the art as shown by their different classification and, as a result, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

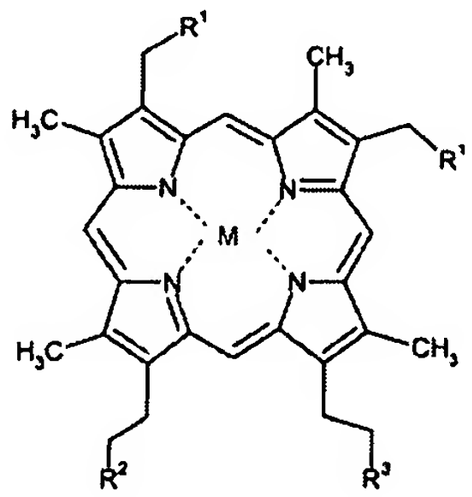
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10 and 17are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,251,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because the prior art disclosure reasonably suggests that which the applicant now claims.

Claim 10 is directed to a pharmaceutical composition comprising a porphyrin complex of formula I as defined below and wherein the variables M, R^1 and R^2 are defined in the applicant's claims, wherein the compounds below is in a pharmaceutically acceptable carrier.



Formula I

Claim 17 is directed to the composition as defined in claim 10 above wherein the porphyrin complex is suspended or dissolved in an aqueous medium.

Platzek et al. in US 6,251,367 teach and claim compounds containing subject matter that overlaps on that which the Applicants currently claim (see US 6,251,367 claim 1). Further,

though the Applicant's current claims are directed to compositions in a pharmaceutically acceptable carrier or suspended in or dissolved in an aqueous medium, the prior art reasonably suggests such compositions. The suggestion of such compositions is found in the prior art examples where the compounds are dissolved in distilled water with sodium chloride to form a saline solution for intravenous use (see column 17 line 12-63).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings above to obtain the compositions as claimed in the instant application. All of the elements of the composition, which are substituted in the instant application, are taught in the art. Obviousness based on similarity of compound structure and functions entails motivation to make the claimed compositions in expectation that compounds similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compositions in searching for new porphyrin compositions not claimed in the prior art patent cited above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek et al. in US 6,251,367 and Crapo et al (US 6,544, 975).

Claim 12 is directed a pharmaceutical composition according to claim 10 as described above, wherein an effective amount of the porphyrin complex is provided to bind peroxynitrite in a body.

The teachings of the compositions disclosed in Platzek et al. are discussed above. Platzek et al., though does not teach the use of such compounds or compositions in binding peroxynitrite in a body. Crapo et al., however, inherently teaches that substituted porphyrin core compounds bind peroxynitrite in the body. It is important to note that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377. The fact that porphyrin core compounds inherently bind peroxynitrite is present in the Crapo et al. reference because it is taught that porphyrin compounds are suitable for modulating intra- and extra-cellular processes wherein peroxynitrite causes oxidative stress (see column 1 lines 59-column 2 line 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings above to obtain the compositions as claimed in the instant application. All of the compounds, which are substituted in the instant application, are taught in the art, and the peroxynitrite binding property is taught in the art. Obviousness based on

similarity of structure and functions entails motivation to make the claimed composition in expectation that compounds similar in structure will have similar properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compositions in searching for new porphyrin core compositions and uses thereof. See In re Payne, 203 USPQ 245 (CCPA 1979).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., Esq.

James O. Wilson, Supervisory Patent Examiner
Art Unit 1623